

Enzymatic Therapy

NATURAL MEDICINES®

December 9, 2003

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM PeriMenopause Formula™*	Take Control of: <ul style="list-style-type: none">• Hot flashes• Night sweats• Low energy• Mood swings• Restless sleep• Irritability• Calcium needs• Inadequate vitamin levels*	<u>AM Formula:</u> Black Cohosh Root Extract, Rhodiola Rosea 3%, Chaste Berry Extract, Green Tea Extract <u>PM Formula:</u> Hops Flower Extract, Black Cohosh Root and Rhizome Extract, L-Theanine, Valerian Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/9/03

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AM/PM Perimenopause 50c

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